

CLAIMS

1. A method of desensitising a patient to a polypeptide allergen the method comprising administering to the patient a peptide derived from the allergen wherein restriction to a MHC Class II molecule possessed by the patient can be demonstrated for the peptide and the peptide is able to induce a late phase response in an individual who possesses the said MHC Class II molecule.
2. A method according to Claim 1 wherein the peptide is included in a composition containing a plurality of peptides derived from the said allergen.
3. A method according to Claim 2 wherein the plurality of peptides derived from said allergen includes peptides for which restriction to Class II DR molecules DR2, DR3, DR4 and DR7 can be demonstrated, provided that such peptides can be derived from the allergen.
- a 4. A method according to ^{Claim 1} ~~any one of Claims 1 to 3~~ wherein the patient possesses any one of the MHC Class II DR molecules DR2, DR3, DR4 or DR7.
5. A method according to ^{Claim 1} ~~any one of Claims 1 to 4~~ wherein the patient possesses the MHC Class II molecule DR4.
6. A method according to Claim 2 wherein the composition contains
7. A method according to Claim 2 wherein the composition contains the soluble MHC Class II-restricted peptides of the Fel d I - derived

peptides described in Figure 9.

8. A composition comprising a plurality of peptides derived from a polypeptide allergen wherein for at least one of the peptides in the composition restriction to a MHC Class II molecule can be demonstrated and the composition is able to induce a late phase response in an individual possessing the given MHC Class II molecule.
9. A composition according to Claim 8 wherein at least one peptide is present in the composition for which restriction to each of MHC Class II DR molecules DR2, DR3, DR4 and DR7 can be demonstrated, provided that such peptides can be derived from the allergen.
10. A composition according to any one of Claims 8 or 9 for use in medicine.
11. A pharmaceutical formulation comprising a composition according to any one of Claims 8 or 9 and a pharmaceutically acceptable carrier.
12. A method according to Claim 1 wherein a composition according to any one of Claims 8 or 9 is administered to the patient.
13. Use of a peptide derived from a polypeptide allergen wherein restriction to a MHC Class II molecule possessed by a patient can be demonstrated by the peptide and the peptide is able to induce a late phase response in an individual who possesses the said MHC Class II molecule in the absence of the allergen.
14. Use of a composition according to any one of Claims 8 or 9 in the

manufacture of a medicament for desensitising a patient to a polypeptide allergen.

Claim 1

15. A method according to ~~any one of Claims 1 to 5 or 12~~, or a
5 composition according to any one of Claims 8 or 9, ~~or a use according to~~
~~Claim 13 or 14~~, or a pharmaceutical preparation according to Claim 11
wherein the polypeptide allergen is any one of Fel d I, Der p I, Der p II,
Der fl or Der flI and allergens present in any of the following: grass, tree
and weed (including ragweed) pollens; fungi and moulds; foods, stinging
10 insects, the chironomidae (non-biting midges); spiders and mites, housefly,
fruit fly, sheep blow fly, screw worm fly, grain weevil, silkworm,
honeybee, non-biting midge larvae, bee moth larvae, mealworm,
cockroach, larvae of *Tenibrio molitor* beetle, mammals such as cat, dog,
horse, cow, pig, sheep, rabbit, rat, guinea pig, mice and gerbil.

15

16. A composition according to any one of Claims 8 or 9, ~~or a use~~
~~according to Claim 13 or 14~~, or a pharmaceutical preparation according to
Claim 11 wherein the polypeptide allergen is Fel d I and as given in SEQ
ID Nos. 1, 2 and 3, or the composition contains the soluble MHC Class
20 II-restricted peptides of the Fel d I - derived peptides described in Figure
9.

17. A method of selecting a peptide for use as an immunotherapeutic
agent for desensitising a patient to a polypeptide allergen capable of
25 eliciting an allergic response in the patient, which patient possesses a
particular MHC Class II molecule, the method comprising the steps of (1)
selecting a candidate peptide derived from the allergen

candidate peptide demonstrates a strong binding to the
particular MHC Class II molecule, and (3) determining whether the candidate
30 peptide is able to induce a late phase response in an individual who

possesses the said MHC Class II molecule.

18. A method according to Claim 17 wherein step (2) is carried out prior to step (3) and only candidate peptides which demonstrate restriction to the particular MHC Class II molecule are selected for testing in step (3).

- a 19. A method according to Claim 18 ~~or 19~~ wherein candidate peptides capable of inducing a late phase response and which demonstrate restriction to the particular MHC Class II molecule are selected as an immunotherapeutic agent.

- a 20. A method according to ^{Claim 17} ~~any one of Claims 17 to 19~~ wherein determination of whether the candidate peptide demonstrates restriction to the said MHC Class II molecule is by using a T cell proliferation assay.

- a 21. A method according to ^{Claim 17} ~~any one of Claims 17 to 20~~ wherein the allergen is selected from the group as defined in Claim 15.

- a 22. A method according to ^{Claim 17} ~~any one of Claims 17 to 21~~ wherein in step (2) determination of whether the candidate peptide demonstrates restriction to the said MHC Class II molecule is by using the patient's cells in a T cell proliferation assay, and in step (3) determining whether the candidate peptide is able to induce a late phase response in the patient.

- 25 a 23. A method according to ^{Claim 17} ~~any one of Claims 17 to 22~~ wherein the MHC molecule is

- 30 24. A peptide when selected by ^{Claim 17} ~~any one of Claims 17 to 23~~.

25. A database of peptides characterised according to their ability to bind an MHC Class II molecule and induce a late phase response in an individual possessing the said MHC Class II molecule.

5

26. A peptide listed in a database according to Claim 25, for use in therapy.

27. A method for selecting a peptide for use as an immunotherapeutic agent for desensitising a patient to an allergen comprising the steps of:

- 10 a) tissue-typing the patient to determine MHC Class II type; and
b) selecting, from a database of peptides which are known to bind to particular MHC Class II molecules and induce a late phase response in an individual possessing such MHC Class II molecules, one or more peptides capable of binding to the MHC Class II molecules possessed by the patient.

28. A method of determining an initial dose of an immunotherapeutic peptide for desensitising a patient to a polypeptide allergen, which peptide is derived from the allergen and wherein restriction to a MHC Class II molecule possessed by the patient can be demonstrated for the peptide and the peptide is able to induce a late phase response in an individual who possesses the said MHC molecule, the method comprising (1) determining the dose which is able to generate an observable late phase response in a given proportion of individuals who possess the said MHC molecule and in whom the peptide is able to induce a late phase response, (2) selecting a dose which is incapable of inducing a late phase response in substantially all individuals who possess the said MHC molecule and in whom the peptide is able to induce a late phase response.

29. A method according to Claim 28 wherein in step (1) the given proportion is 50%.

a 5 30. A method according to Claims 28 ~~or 29~~ wherein the lower dose is 0.01% of the dose which is able to generate an observable late phase response in the given proportion of individuals.

a 10 31. A method according to ^{claim 28} ~~any one of Claims 28 to 30~~ wherein in steps (1) and (2) the peptide is included in a plurality of peptides derived from the said allergen.

Adel
25